

IN THE CLAIMS

The following listing replaces all prior listings and versions of the pending claims. Any claim that is cancelled or subject matter deleted from a claim is effected without prejudice

1. (Withdrawn) In a method for preparing an oral sustained release pharmaceutical composition in solid dosage form having a desired drug release profile, which pharmaceutical composition is prepared by mixing a drug in a therapeutically effective amount with an effective amount of a sustained release carrier to retard the release of the drug from the pharmaceutical composition and a water insoluble or partially water insoluble cellulose in an amount effective to enhance the ability of the pharmaceutical composition to form the solid dosage form, resulting in a pharmaceutical composition having a drug release profile exhibiting a faster release than that of the desired drug release profile, the improvement comprising adding to the pharmaceutical composition an effective amount of a maltodextrin to retard the rate of release of the drug in the sustained release pharmaceutical composition to the desired drug release profile when placed in aqueous system, the weight ratio of the maltodextrin to the water insoluble or partially water insoluble cellulose that is added to enhance tableting ranging from about 1:50 to about 50:1.

2. (Withdrawn) The improved method according to Claim 1 wherein the water insoluble or partially water insoluble cellulose is starch or microcrystalline cellulose.

3. (Withdrawn) The improved method according to Claim 1 wherein the cellulose is microcrystalline cellulose.

4. (Withdrawn) The improved method according to Claim 3 wherein the cellulose is silicified microcrystalline cellulose.

5. (Withdrawn) The improved method according to Claim 1 additionally containing additives.

6. (Withdrawn) The improved method according to Claim 1 wherein the sustained release carrier is polymethylacrylate.

7. (Withdrawn) The improved method according to Claim 1 wherein the sustained release carrier is a mixture of cellulose ether and xanthan gum in a weight ratio ranging from about 1:01 to about 1:2.

8 (Withdrawn) The method according to Claim 7 wherein the cellulose ether is hydropropylmethyl cellulose.

9. (Withdrawn) The improved method according to any one of Claims 1-8, wherein the weight ratio of maltodextrin to cellulose ranges from about 1:20 to about 20:1.

10. (Withdrawn) The improved method according to Claim 9, wherein the weight ratio of maltodextrin to cellulose ranges from 1:9 to about 9:1.

11. (Withdrawn) The improved method according to Claim 1 wherein the sum of the maltodextrin and the cellulose ranges from about 5 to about 95% of the pharmaceutical composition.

12. (Withdrawn) In a method for preparing an oral sustained release pharmaceutical composition in tablet form having a desired drug release profile, which pharmaceutical composition is prepared by mixing a drug in a therapeutically effective amount, an effective amount of an sustained release carrier to retard the release of the drug from the pharmaceutical composition and a lubricating effective amount of a lubricant with a tableting effective amount of microcrystalline cellulose to enhance the ability of the pharmaceutical composition to form a tablet, resulting in a pharmaceutical composition having a drug release profile having a faster release than that of the desired drug release profile, the improvement comprising adding to the pharmaceutical composition an effective amount of maltodextrin to retard the rate of release of

the drug in the sustained release pharmaceutical composition to the desired drug release profile when placed into an aqueous system, the weight ratio of the maltodextrin to the microcrystalline cellulose that is added to enhance the tableting ranging from about 1:50 to about 50:1.

13. (Withdrawn) The improved method according to Claim 12 wherein the cellulose is silicified microcrystalline cellulose.

14. (Withdrawn) The improved method according to Claim 12 additionally containing additives.

15. (Withdrawn) The improved method according to Claim 12 wherein the sustained release carrier is polymethylacrylate.

16. (Withdrawn) The improved method according to Claim 12 wherein the sustained release carrier is a mixture of cellulose ether and xanthan gum in a weight ratio ranging from about 1:01 to about 1:2

17. (Withdrawn) The method according to Claim 16 wherein the cellulose ether is hydropropylmethyl cellulose.

18. (Withdrawn) The improved method according to Claim 1 wherein the sustained release carrier is a mixture of cellulose ether and xanthan gum, such that the xanthan gum is present in the pharmaceutical formulation in an amount ranging from 3% to about 7% by weight of the tablet, said cellulose ether being present in an amount ranging from about 3% to about 20% by weight of the tablet, and the water insoluble cellulose is silicified microcrystalline cellulose, the weight ratio of maltodextrin to silicified microcrystalline cellulose ranging from about 1:20 to about 20:1.

19. (Withdrawn) The improved method according to Claim 18 wherein the weight ratio of maltodextrin to silicified microcrystalline cellulose ranges from about 1:9 to about 9:1

20. (Withdrawn) The improved method according to Claim 18 or 19 wherein the cellulose ether is hydroxypropylmethyl cellulose.

21. (Withdrawn) The improved method according to Claim 1 or 18 wherein the drug is metformin.

22. (Withdrawn) The improved method according to Claim 1 or 18 wherein the drug is carbamazepine.

23. (Withdrawn) The improved method according to Claim 1 or 18 wherein the drug is metroindazole, and the sustained release carrier is polymethacrylate.

24. (Withdrawn) The improved method according to Claim 21 wherein the weight ratio of the maltodextrin to the microcrystalline cellulose ranges from about 1:9 to about 9:1.

25. (Withdrawn) The improved method according to Claim 22 wherein the weight ratio of the maltodextrin to the microcrystalline cellulose ranges from about 1:9 to about 9:1.

26. (Withdrawn) The improved method according to Claim 23 wherein the weight ratio of the maltodextrin to the microcrystalline cellulose ranges from about 1:9 to about 9:1.

27. (Withdrawn) A method of reducing the release profile of a drug in an aqueous medium in a controlled release pharmaceutical composition which pharmaceutical composition comprises a therapeutically effective amount of a medicament, a controlled release carrier and said method comprising adding thereto a partially water soluble or water insoluble cellulose in amounts sufficient to enhance the tableting ability of said pharmaceutical composition and maltodextrin in an amount sufficient to retard the release profile.

28. (Withdrawn) The method according to Claim 27 wherein the weight ratio of said cellulose to maltodextrin ranges from amount 1:50 to about 50:1.

29. (Withdrawn) The method according to Claim 27 wherein the water insoluble or partially soluble cellulose is starch or silicified microcrystalline cellulose.

30. (Withdrawn) The method according to Claim 27 additionally containing adjuvants.

31. (Withdrawn) The method according to Claim 27 wherein the sustained release carrier is polymethylacrylate.

32. (Withdrawn) The method according to Claim 27 wherein the sustained release carrier is a mixture of a cellulose ether and xanthan gum in a weight ratio ranging from about 1:01 to about 1:2

33. (Withdrawn) The method according to Claim 32 wherein the cellulose ether is hydropropylmethyl cellulose.

34. (Withdrawn) The improved method according to Claim 28, wherein the weight ratio of the water insoluble or partially soluble cellulose to maltodextrin ranges from about 1:20 to about 20:1.

35. (Withdrawn) The method according to Claims 28, wherein the weight ratio of water insoluble or partially soluble cellulose to maltodextrin ranges from about 1:9 to about 9:1.

36. (Withdrawn) The method according to Claim 27 wherein the sum of the maltodextrin and the cellulose ether ranges from about 5 to about 90% of the pharmaceutical composition.

37. (Withdrawn) The method according to any one of Claims 1, 12 and 27 wherein the sustained release carrier is a hydrophilic polymer, hydrophobic polymer or wax polymer.

38. (Currently Amended) A sustained release pharmaceutical composition in oral dosage form comprising a pharmaceutically effective amount of a drug, a sustained release carrier in an effective amount to retard the release of the drug from said composition when

placed in an aqueous system, ~~a lubricating effective amount of a lubricant~~, a water insoluble or partially water insoluble cellulose, ~~and maltodextrin and optionally a lubricating effective amount of a lubricant~~, wherein the weight ratio of cellulose to maltodextrin ranges from about 50:1 to 1:50.

39. (Cancelled)

40. (Currently Amended) The sustained release pharmaceutical composition according to Claim 38 wherein the sustained release polymer is a mixture of cellulose ether and xanthan gum.

41. (Currently Amended) The sustained release pharmaceutical composition according to Claim 40 wherein the weight ratio of cellulose ether to xanthan gum ranges from about 1:0.1 to about 1:2.

42. (Currently Amended) The sustained release pharmaceutical composition according to Claim 40 wherein the cellulose ether is hydroxypropylmethyl cellulose.

43. (Currently Amended) The sustained release pharmaceutical composition according to Claim 38 wherein the weight ratio of cellulose to maltodextrin ranges from about 20:1 to about 1:20.

44. (Currently Amended) The sustained release pharmaceutical composition according to Claim 43 wherein the weight ratio of cellulose to maltodextrin ranges from about 9:1 to about 1:9.

45. (Currently Amended) The sustained release pharmaceutical composition according to Claim 38 wherein the drug is metformin, metronidazole or carbamazepine or mesalamine.

46. (Currently Amended) The sustained release pharmaceutical composition according to Claim 38 wherein the water insoluble or partially water insoluble cellulose is starch or microcrystalline cellulose.

47. (Currently Amended) The sustained release pharmaceutical composition according to Claim 46 wherein the water insoluble or partially water insoluble cellulose is microcrystalline cellulose.

48. (Currently Amended) The sustained release pharmaceutical composition according to Claim 47 wherein the microcrystalline cellulose is silicified microcrystalline cellulose.

49. (Withdrawn) A method of treating a disease in a patient requiring a sustained release formulation of a drug for treating said disease, said treatment comprising administering to the patient a pharmaceutically effective amount of the sustained release pharmaceutical composition according to any one of Claims 38-48.

50. (Withdrawn) The improved method according to Claim 1 wherein the sustained release carrier is glyceryl behenate.

51. ((Withdrawn) The improved method according to Claim 12 wherein the sustained release carrier is glyceryl behenate.

52. ((Withdrawn) The method according to Claim 27 wherein the sustained release carrier is glyceryl behenate.

53. ((Withdrawn) The sustained release pharmaceutical composition according to Claim 38 wherein the sustained release carrier is glyceryl behenate.

54. (Original) The sustained release pharmaceutical composition according to Claim 38 wherein the sum of the maltodextrin and the cellulose ranges from about 5% to about 95% by weight of the pharmaceutical composition.

55. (Original) The sustained release pharmaceutical composition according to Claim 54 wherein the sum of the maltodextrin and the cellulose ranges from about 10% to about 60% by weight of the pharmaceutical composition.

56. (Previously Amended) The sustained release pharmaceutical composition according to Claim 55 wherein the sum of the maltodextrin and the cellulose ranges from about 20% to about 50% by weight of the pharmaceutical composition.

57. (Withdrawn) The improved method according to Claim 1 wherein the solid dosage oral form is a pellet, tablet or capsule.

58. (Withdrawn) The method according to Claim 27 wherein the solid dosage oral form is a pellet, tablet or capsule.

59. (Currently Amended) The sustained release pharmaceutical composition according to Claim 38 wherein the solid unit dosage oral form is a pellet, tablet or capsule.

60. (Currently Amended) The sustained release pharmaceutical composition according to the Claim 38 wherein the sustained release carrier is a hydrophilic polymer.

61. (Withdrawn) The pharmaceutical composition according to Claim 38 wherein the sustained release carrier is a hydrophobic polymer.

62. (Withdrawn) The pharmaceutical composition according to Claim 38 wherein the sustained release carrier is a wax polymer.

63. (New) The sustained release pharmaceutical composition according to Claim 43 wherein the cellulose is microcrystalline cellulose.

64. (New) The sustained release pharmaceutical composition according to Claim 44 wherein the cellulose is microcrystalline cellulose.

65. (New) The sustained release pharmaceutical composition according to Claim 55 wherein the cellulose is microcrystalline cellulose.

66. (New) The sustained release pharmaceutical composition according to Claim 56 wherein the cellulose is microcrystalline cellulose.

67. (New) The sustained release pharmaceutical composition according to Claim 63 wherein the microcrystalline cellulose is silicified microcrystalline cellulose.

68. (New) The sustained release pharmaceutical composition according to Claim 64 wherein the microcrystalline cellulose is silicified microcrystalline cellulose.

69. (New) The sustained release pharmaceutical composition according to Claim 65 wherein the microcrystalline cellulose is silicified microcrystalline cellulose.

70. (New) The sustained release pharmaceutical composition according to Claim 66 wherein the microcrystalline cellulose is silicified microcrystalline cellulose.